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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,367	10/20/2003	Shigeru Nemoto	WAKAB60.001DV1	2857
20995	7590	11/16/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			WILLIAMS, CATHERINE SERKE	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			3763	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/689,367	<b>Applicant(s)</b> NEMOTO, SHIGERU	
	<b>Examiner</b> Catherine S. Williams	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/26/04; 9/9/05</u> | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3-6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly et al (USPN 4,677,980) in view of Fago et al (USPN 6,569,127).

Reilly discloses a cylinder holder (14') that includes a positioning mechanism (126) being a blade spring (128) with a pawl/latch (126a). See Figure 15. The positioning mechanism (126a) is adapted to engage a concave portion (136) provided on a portion (16') of the syringe barrel (18). See 8:55-9:66. The cylinder holder (14') is provided directly on the front of the injection apparatus (10). See figures 1 and 7. The cylinder holder (14') is an adapter (in that it is a separate attachment component) to which the syringe barrel (18) can be mounted when the adapter is set in the injection apparatus. See 14' set in notches (60a and b)) in figure 1. The device also includes insertion pins (124) which are adapted to fix the syringe barrel by holding a flange on the syringe barrel. See Figure 15 and 8:34-9:13.

Regarding the claim 1 language of "the positioning mechanism adapted to engage a concave portion provided on the syringe barrel when the flange is inserted into the flange insertion groove and rotated to a use position", see 8:55-65. "The peripheral flange 132...is rotated slightly counterclockwise, as viewed in figure 15...so that spring detent member 126 riders into a small retaining notch 136 in the flange."

Regarding the claim 6 language of “wherein the flange on the syringe barrel is capable of being inserted into the flange insertion groove in the state that the syringe barrel and a syringe piston is coupled...”, see figure 15. Figure 15 clearly shows a mounted syringe barrel (18) and a syringe piston (38-2) inserted into the barrel. The piston (38-2) has a rod (88).

Reilly meets the claim limitations as described above but fails to include the cylinder holder having an insertion groove.

However, Fago discloses a syringe and injector system that includes a syringe barrel (12) with a flange (16a,16b). The syringe is held by an injector having a cylinder holder (10). See figure 1. In this embodiment, the cylinder holder (10) has two grooves (26a,26b) that fix the syringe barrel by holding the flange of the barrel. See figure 1.

At the time of the invention, it would have been obvious to one skilled in the art to substitute the pin/flange attachment of Reilly with the teaching of a groove/flange attachment of Fago. Both devices are analogous in the art of syringe injection systems and both have front-loading syringe barrels; therefore, a combination is proper. Additionally, the pins of Reilly and the grooves of Fago are functional equivalents designed for the same purpose and to solve the same problem, i.e. attachment of the syringe to the front of the injector. Furthermore, one skilled in the art would recognize that the flange/groove attachment of Fago has additional surface area for frictional contact. This added function enhances the design and performance of the flange/groove attachment over the pin/flange attachment by enhancing the mechanical contact of the syringe with the injector and thereby reducing the chance of the syringe from inadvertently becoming dislodged from the injector. The motivation for the incorporation is garnered from the fact that the structures are functional equivalents. Additionally, one skilled in the art would

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recognize this equivalency. The teaching of a flange/groove attachment would be incorporated to achieve the same function as the pin/flange attachment in addition to enhancing the mechanical stability of the connection.

Regarding the claim 6 language of "...wherein said syringe can be mounted on the cylinder holder from the direction parallel to the insertion grooves", see in part Reilly figure 15 and 8:60-66. As shown, the syringe (16' portion) is mounted in a rotational direction onto the holder (14'). See Reilly 8:60-66. In view of the substitution above, the substituted insertion grooves (see Fago 26a,26b) have a rotational track. Hence, the mounting direction of the device in combination has is a direction parallel to the direction of the insertion grooves.

Claims 2 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly in view of Fago in further view of Rait (USPN 5,429,611). Reilly in view of Fago meets the claim limitations as described above including the teaching of a positioning mechanism (126) being a blade spring (128) with a pawl/latch (126a) but fails to teach that the blade spring could be a coil spring.

However, Rait discloses a syringe with pivotable latches/pawls (20) that are biased by a coiled spring (28). See figures 1 and 3. Rait discloses that the coil spring could be substituted with a leaf spring. See 5:58-62.

At the time of the invention, it would have been obvious to one skilled in the art to substitute the blade spring of Reilly in view of Fago with the teaching of the coil spring by Rait. Blade/leaf and coil springs are well known in the syringe/injector art and are commonly used to bias structural components relative to one another. One skilled in the art would recognize each

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are used interchangeably and are commonly substituted for one another. See Rait 5:58-62. Additionally, one skilled in the art recognizes that blade/leaf springs are prone to repetitive failure due to their cantilevered structure and can easily fracture at the fulcrum of the spring. Reilly in view of Fago discloses a repetitive use device where the spring would be subject to repetitive failure. Coil springs, albeit can fail, but do not have a single point/ focus of bending and weakness and can better withstand repetitive use than a leaf/blade spring.

Therefore at the time of the invention, it would have been obvious to substitute the blade/leaf spring of Reilly in view of Fago for a coiled spring as taught by Rait in view of common knowledge known by one skilled in the art. The motivation for the substitution would have been in order to provide a spring with enhanced performance for repetitive use.

### *Response to Arguments*

Applicant's arguments filed 7/11/05 have been fully considered. The arguments regarding the Armsbruster reference are moot in light of the withdrawal of the rejection. The arguments regarding the Reilly in view of Fago and Reilly in view of Fago in view of Reit rejections are not persuasive.

Regarding the Reilly in view of Fago rejection, see rejection above for the amended claim language. Applicant argues that Reilly does not teach a concave portion on a syringe but rather a concave portion on a pressure jacket that houses a syringe and therefore does not teach the limitation of “a positioning mechanism on the cylinder holder adapted to engage a concave portion provided on the syringe barrel”. This argument is not persuasive because (i) the limitation of the syringe and limitations corresponding to the syringe are functional limitations of

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the claims and (ii) the prior art reads on the positive structural limitation of the claims, i.e. positioning mechanism, which is capable of providing the claimed function, i.e. engage a concave portion provided on the syringe barrel.

A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The only positively claimed limitations are the flange insertion groove and a positioning mechanism. The positioning mechanism, i.e. element 126 of Reilly see above, is capable of engaging “a concave portion provided on a syringe barrel when a flange of the syringe is inserted into the flange insertion groove and rotated to a use position” since Reilly shows the positioning mechanism engaging a concave portion (136) provided on a flange (16') on a syringe (18) when the flange (16') is rotated. See Reilly 8:60-66. Elements 136, 16' and 18 of Reilly are the functionally included syringe and therefore show that Reilly is capable of achieving the claimed function. Reilly does not have to teach the functionally claimed syringe to meet the claim limitations.

Regarding the Reilly in view of Fago in view of Reit rejection, applicant argues that since the Reilly in view of Fago rejection does not teach all the claim limitations the addition of the Reit reference does not render claim 2 obvious. Regarding the Reilly in view of Fago rejection and arguments, see above.

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

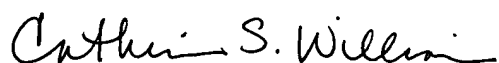
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine S. Williams  
November 1, 2005